immune response toward a Th1 type or mixed Th1/Th2 type response utilizing *Klebsiella pneumonia* membrane fractions combined with an antigen or hapten, and compositions related thereto. The Examiner may withdraw non-elected claims without prejudice to their rejoinder during later examination and/or prosecution in a Divisional Application.

In addition, the applicants have converted elected European 'use' claims into U.S. 'method' claims to conform with USPTO preferences. The applicants have also converted European 'use' claims which were directed to a pharmaceutical composition, into proper U.S. form pharmaceutical composition claims.

* * * * *

Accordingly, entry of the present Amendment and Election into the record of this application, and favorable action on the merits thereof, are respectfully solicited.

Respectfully submitted,
THE FIRM OF HUESCHEN AND SAGE

By: G. PATRICK SAGE
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Dated: April 18, 2003
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Enclosure: Postal Card Receipt, and Amended Claims in both 'Clean' and Marked-Up' form

* * * * *

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.

CLAIMS (Marked-Up Form)

We Claim:

- 34 -

A method of orienting an immune response toward a Th1 type and/or mixed Th1/Th2 type response directed against an antigen or hapten, in which response the Th1 response is close to or greater than the Th2 response, comprising the step of administering to a living animal body an amount of [The use of] a *Klebsiella pneumonia* membrane fraction combined with the antigen or hapten [for the preparation of a pharmaceutical composition] which is effective in [intended to orient] orienting the immune response toward a Th1 type and/or mixed Th1/Th2 type response directed against the antigen or hapten, in which response the Th1 response is close to or greater than the Th2 type response.

- 35 -

The method [use] of Claim 34, wherein the membrane fraction comprises at least membrane fractions of two different bacterial strains.

- 38 -

The method [use] of Claim 34, wherein the antigen or hapten is chosen from the antigens or haptens specific to an infectious agent or from the antigens associated with tumor cells.

- 39 -

The method [use] of Claim 38, wherein the antigen or hapten is chosen from peptides, lipopeptides, polysaccharides, oligosaccharides, nucleic acids, lipids or any compound capable of specifically directing the Th1 type and/or mixed Th1/Th2 type immune response against an antigen or hapten specific to an infectious agent or an antigen associated with a tumor cell.

- 40 -

The method [use] of Claim 34, wherein the antigen or hapten is coupled or mixed with the membrane fraction.

- 41 -

The method [use] of Claim 34, wherein the antigen or hapten is covalently coupled with a supporting peptide to form a complex capable of specifically binding to mammalian serum albumin.

- 42 -

The method [use] of Claim 41, wherein the supporting peptide is a peptide fragment derived from streptococcal G protein.

- 43 -

The method [use] of Claim 41, wherein the complex is prepared by genetic recombination.

- 44 -

The method [use] of Claim 41, wherein the antigen, hapten or complex is covalently coupled with at least one of the compounds contained in the membrane fraction.

- 45 -

The method [use] of Claim 44, wherein the covalent coupling is a coupling carried out by chemical synthesis.

- 46 -

The method [use] of Claim 45, wherein one or more linking elements are introduced into at least one of the compounds contained in the membrane fraction and/or in the antigen, hapten or complex to facilitate the chemical coupling.

- 47 -

The method [use] of Claim 46, wherein the linking element introduced is an amino acid.

- 48 -

The method [use] of Claim 44, wherein the coupling between the antigen, hapten or complex and at least one of the compounds contained in the membrane fraction, is carried out by genetic recombination when the antigen, hapten or complex and the membrane compound are of a peptide nature.

- 49 -

The [use]pharmaceutical composition of Claim [34] 72, wherein the [pharmaceutical] composition comprises an agent which makes it possible to carry the membrane fraction associated with the antigen, hapten or complex in a form which makes it possible to enhance its stability and/or its immunogenicity [immunogenecity].

- 50 -

The [use] pharmaceutical composition of Claim 49, wherein the agent is an oil-in-water or water-in-oil type emulsion.

- 51 -

The [use] pharmaceutical composition of Claim 49, wherein the agent is a particle of the liposome, microsphere or nanosphere type or any type of structure allowing the encapsulation and the presentation in particulate form of the membrane fraction associated with the antigen, hapten or complex.

- 52 -

The [use] pharmaceutical composition of Claim 49, wherein the agent is chosen from aluminum salts, calcium salts, compounds of plant origin such as Quil A or saponin, or compounds of bacterial origin such as cholera, pertussis or tetanus toxoid or thermolabile E. coli toxin.

- 53 -

The [use] pharmaceutical composition of Claim [34] 72, wherein the pharmaceutical composition comprises an agent which makes it possible to regulate the immune response induced by the membrane fraction associated with the antigen, hapten or complex.

- 54 -

The [use] pharmaceutical composition of Claim 53, wherein the regulatory agent is chosen from cytokines, growth factors, hormones or cellular components such as nucleic acids, a protein of the family of heat shock proteins or ribosomes.

- 72-

A pharmaceutical composition comprising a *Klebsiella pneumonia* membrane fraction combined with an antigen or hapten, which is effective in orienting an immune response toward a Th1 type and/or mixed Th1/Th2 type response directed against the antigen or hapten, in which response the Th1 response is close to or greater than the Th2 type response, with a pharmaceutically acceptable carrier, diluent and /or additive.